REMARKS

I. Introduction

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons below.

II. Status of the Claims and Summary of Amendments

Claims 1-50 were cancelled previously. No claims are presently cancelled. Claim 51 is amended to specify that the claimed composition has a pH within the range of 5.0 to 6.0. Exemplary support for the amendment can be found in the specification, for instance, at page 7, lines 21-22.

After entry of the foregoing amendments, claims 51-59 will be pending. The amendments do not introduce new matter or warrant further searching. Indeed, the recited pH range already was recited in claim 56. Moreover, the amendments eliminate or at least reduce the number of issues for appeal. Accordingly, Applicants respectfully request entry of the amendments after final.

III. The Office Action

The PTO withdrew all but one outstanding ground for rejection (Office Action at page 2). The remaining issue is the PTO's allegation that claims 51-59 are unpatentable under 35 U.S.C. § 103(a) over Pathak in view of Benneker and Chu (*id.*). Applicants respectfully traverse the rejection insofar as it might pertain to the claims as amended.

The claims are patentable over the cited prior art for at least the reason that the references, alone or in combination with each other, fail to teach or suggest a pharmaceutical composition comprising a sulfonate salt of paroxetine, calcium hydrogen phosphate anhydrate in the form of plate shaped crystals or agglomerates thereof, a disintegrant and a lubricant, wherein said composition does not contain lactose or microcrystalline cellulose, and wherein said composition has a pH within the range of 5.0 to 6.0, as recited in independent claim 51, or a pharmaceutical composition comprising a sulfonate salt of paroxetine, calcium hydrogen phosphate anhydrate in the form of plate shaped crystals or agglomnerates thereof, a disintegrant and a lubricant, wherein said composition has a pH within the range of 5.0 to 6.0 and said composition has an added water content of 1.2 wt% or less, as recited in independent claim 56.

For example, the cited references, alone or in combination with each other, fail to teach or suggest such a pharmaceutical composition that has a pH in the recited range of 5.0 to 6.0. Applicants' previous response emphasized that not only do the references fail to teach pH of a composition, they fail to mention pH at all in any connection with such a composition. Therefore, in contrast to the PTO's stated ground for rejection, pH is not taught in the cited art as a parameter to adjust, much less to adjust to the recited range of 5.0 to 6.0. Accordingly, it would not have been obvious to adjust pH, indeed even to optimize it.

In the present Office Action, the PTO alleged that the "tertiary reference," presumably Chu, discloses "pH parameters in making the products disclosed therein" (Office Action at page 4). The PTO further relied upon disclosure in Chu concerning adjustment of pH from 3 to neutral (*id.*). Therefore, the PTO concluded that such disclosure would have motivated the skilled artisan to adjust pH of "the composition" (*id.*).

The rejection fails to appreciate that Chu's discussion of pH concerns the pH of an aqueous solution that yields a *dicalcium phosphate product*, whereas the present claims recite the pH of a sulfonate salt pharmaceutical composition. Thus, the reference to pH in Chu is made in a context completely different from that of the presently recited pH range.

Specifically, the passage cited by the PTO characterizes the preparation of dicalcium phosphate by boiling DCPD at a pH below 5.5, and the reference describes the resulting crystal sizes and shapes when the pH is adjusted to lower values (*see* Chu at col. 2, lines 3-8). Thus, the pH taught by Chu refers only to an aqueous solution from which dicalcium phosphate is crystallized. Chu does not teach or suggest any pH range or adjustment thereof that pertains, as here, to pharmaceutical compositions.

A recent precedential decision by the Board of Patent Appeals and Interferences further supports Applicant's position. In *Ex parte Whalen II*, App. 2007-4423 (July 23, 2008) (copy attached), the Board explained that "where the parameter optimized was not recognized in the prior art as one that would affect the results," the doctrine of routine optimization does not apply. *Whalen II*, slip op. at 14. Moreover, where there is no evidence of record that "would support the conclusion that those skilled in the art would have considered it obvious to 'optimize' [the parameter at issue] . . . to the level recited in the claims," a finding of obviousness is improper. *Id.* The Board explained, "Obviousness cannot be proven merely by showing that a known composition could have been modified by routine experimentation or solely on the expectation of success; it must be shown that

those of ordinary skill in the art would have had some apparent reason to modify the known composition in a way that would result in the claimed composition." *Id.* at 16. Here, where the record reveals no such reason, there is no *prima facie* case of obviousness, and the §103 rejection should be withdrawn.

In summary, for the reasons of record, none of the cited references alone or in combination teach or suggest the claimed compositions. The references moreover fail to hint at the recited pH range of 5.0 to 6.0. Further, because the references do not mention pH at all in connection with pharmaceutical compositions, adjustment of pH is not an obvious modification that would yield the claimed compositions. Therefore, the person who is skilled in the art would not consider the compositions to be obvious. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

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Having advanced credible grounds for the withdrawal of the only rejection of record, Applicants believe that the present application is in condition for allowance. Applicants therefore respectfully request favorable reconsideration of the application. The Examiner is courteously invited to contact Applicants' undersigned attorney by telephone at the number below if the Examiner believes that any remaining issue warrants a discussion.

Respectfully submitted,

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The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.